LISTING OF THE CLAIMS:

This Listing of the Claims will replace all prior versions, and listings, of the claims in the present application.

1-69. (Canceled)

70. (Currently Amended) A sustained-release oral dosage form comprising an extruded blend of:

hydromorphone hydrochloride ~~or a pharmaceutically acceptable salt thereof~~;

one or more hydrophobic materials, said hydrophobic materials being ~~selected from the group consisting of alkylcelluloses,~~ acrylic and methacrylic acid polymers and copolymers~~, shellac, zein, hydrogenated castor oil, hydrogenated vegetable oil, and mixtures thereof~~; and

one or more hydrophobic fusible carriers having a melting point from about 30 °C to about 200 °C, said hydrophobic fusible carriers being ~~and selected from the group consisting of natural or synthetic waxes,~~ fatty acids, fatty alcohols, ~~and~~ or mixtures thereof,

wherein the extrude blend is divided into a unit dose containing an effective amount of hydromorphone to render a desired therapeutic effect and providing a sustained-release of hydromorphone for a time period from about 8 to about 24 hours,

and wherein the oral dosage form, when containing about 8 mg hydromorphone hydrochloride ~~or its pharmaceutically acceptable salt~~, provides an in-vivo plasma concentration versus time curve (in the fasted state) having an AUC from about 15.83 to about 19.23 ng·hour/ml, ~~which is about 96-132% of the AUC observed when an immediate release formulation of the same dosage is administered,~~ a C_{max} from about 0.52 to about 0.76 ng/ml, ~~which is about 16-21% of the C_{max} observed when an immediate release formulation of the same dosage is administered,~~ and a T_{max} from about 3.9 to about 6.8 hours~~, which is about 557-971% of the T_{max} observed when an immediate release formulation of the same dosage is administered~~.

71. (Currently Amended) A sustained-release oral dosage form comprising an extruded blend of:

hydromorphone hydrochloride ~~or a pharmaceutically acceptable salt thereof~~;

one or more hydrophobic materials, said hydrophobic materials being ~~selected from the group consisting of alkylcelluloses,~~ acrylic and methacrylic acid polymers and copolymers, ~~shellac, zein, hydrogenated castor oil, hydrogenated vegetable oil, and mixtures thereof~~; and

one or more hydrophobic fusible carriers having a melting point from about 30 °C to about 200 °C, said hydrophobic fusible carriers being ~~and selected from the group consisting of natural or synthetic waxes,~~ fatty acids, fatty alcohols, ~~and~~ or mixtures thereof,

wherein the extrude blend is divided into a unit dose containing an effective amount of hydromorphone to render a desired therapeutic effect and providing a sustained-release of hydromorphone for a time period from about 8 to about 24 hours,

and wherein the oral dosage form, when containing about 8 mg hydromorphone hydrochloride ~~or its pharmaceutically acceptable salt~~, provides an in-vivo plasma concentration versus time curve (in the fed state) having an AUC from about 16.55 to about 21.47 ng·hour/ml, a C_{max} of from about 0.65 to about 0.93 ng/ml, and a T_{max} of from about 1.9 to about 4.1 hours.

72. (Currently Amended) The oral dosage form of claim 70 or 71, wherein the extruded blend is formed by mixing the hydromorphone hydrochloride ~~or its pharmaceutically acceptable salt~~, the one or more hydrophobic materials, and the one or more hydrophobic fusible carriers in an extruder to form the blend and extending the blend through the extruder.

73. (Currently Amended) The oral dosage form of claim 72, wherein the hydromorphone hydrochloride ~~or its pharmaceutically acceptable salt~~, the one or more hydrophobic materials, and the one or more hydrophobic fusible carriers enter said extruder in powder form.

74. (Currently Amended) The oral dosage form of claim 72, wherein the hydromorphone hydrochloride ~~or its pharmaceutically acceptable salt~~, the one or more hydrophobic materials, and the one or more hydrophobic fusible carriers, all in powder form, are mixed to form a powder mixture prior to entering the extruder.

75. (Previously Presented) The oral dosage form of claim 72, wherein the blend is subjected to sufficient amount of heat to sufficiently soften the blend during the extrusion process.

76. (Previously Presented) The oral dosage of claim 72, wherein the extruded blend is substantially non-porous.

77. (Previously Presented) The oral dosage form of claim 72 wherein the extrudate has a diameter of from about 0.1 to about 5 mm.

78. (Previously Presented) The oral dosage form of claim 72, wherein the extrudate comprises a strand-shaped matrix cut into multi-particulates having a length of from about 0.1 to about 5 mm in length.

79. (Previously Presented) The oral dosage form of claim 78, wherein a unit dose comprising an effective amount of the multi-particulates is compressed into a tablet.

80. (Previously Presented) The oral dosage form of claim 78, wherein a unit dose comprising an effective amount of the multi-particulates is contained within a gelatin capsule.

81. (Previously Presented) The oral dosage form of claim 72, wherein the hydrophobic fusible carrier has a melting point from about 45 °C to about 90 °C.

82. (Previously Presented) The oral dosage form of claim 72, further comprising a plasticizer.

83. (Previously Presented) The oral dosage form of claim 82, wherein the plasticizer is selected from the group consisting of diethyl phthalate, tributyl citrate, triacetin, and mixtures thereof.

84. (Previously Presented) The oral dosage form of claim 72, further comprising a lubricant.

85. (Previously Presented) The oral dosage form of claim 84, wherein the lubricant is selected from the group consisting of magnesium stearate, stearic acid, talc, and mixtures thereof.

86. (Cancelled)

87. (Currently Amended) A method of preparing a sustained-release oral dosage form, comprising:

blending in an extruder hydromorphone hydrochloride ~~or a pharmaceutically acceptable salt thereof~~ together with: (1) ~~a~~ one or more hydrophobic ~~material~~ materials, said hydrophobic materials being ~~selected from the group consisting of alkylcelluloses,~~ acrylic and methacrylic acid polymers and copolymers~~, shellac, zein, hydrogenated castor oil, hydrogenated vegetable oil~~; and (2) ~~a~~ one or more hydrophobic fusible carriers ~~carrier selected from the group consisting of natural or synthetic waxes, fatty acids, fatty alcohols, and mixtures thereof, the hydrophobic fusible carrier~~ having a melting point ~~between 30-200 °C~~ from about 30 °C to about 200 °C and being included in an amount sufficient to further slow the release of the hydromorphone, said hydrophobic fusible carriers being fatty acids, fatty alcohols, or mixtures thereof;

heating the blend to a temperature sufficient to soften the mixture sufficiently to extrude the same;

extruding the heated mixture as a strand having a diameter from ~~0.1-5~~ about 0.1 mm to about 5 mm;

cooling the strand; dividing the strand to form non-spheroidal multi-particulates of the extrudate having a length from ~~0.1-5~~ about 0.1 mm to about 5 mm; and

dividing the non-spheroidal multi-particulates into unit doses,

wherein the oral dosage form, when containing about 8 mg hydromorphone hydrochloride ~~or its pharmaceutically acceptable salt~~, provides an in-vivo plasma concentration versus time curve (in the fasted state) having an AUC from about 15.83 to about 19.23 ng·hour/ml, ~~which is about 96-132% of the AUC observed when an immediate release formulation of the same dosage is administered,~~ a C_{max} from about 0.52 to about 0.76 ng/ml, ~~which is about 16-21% of the C_{max} observed when an immediate release formulation of the same dosage is administered,~~ and a T_{max} from about 3.9 to about 6.8 hours~~, which is about 557-971% of the T_{max} observed when an immediate release formulation of the same dosage is administered~~.

88. (Currently Amended) A method of preparing a sustained-release oral dosage form, comprising:

blending in an extruder hydromorphone hydrochloride ~~or a pharmaceutically acceptable salt thereof~~ together with: (1) ~~a~~ one or more hydrophobic ~~material~~ materials, said hydrophobic materials being ~~selected from the group consisting of alkylcelluloses,~~ acrylic and methacrylic acid polymers and copolymers~~, shellac, zein, hydrogenated castor oil, hydrogenated vegetable oil~~; and (2) ~~a~~ one or more hydrophobic fusible carriers ~~carrier selected from the group consisting of natural or synthetic waxes, fatty acids, fatty alcohols, and mixtures thereof, the hydrophobic fusible carrier~~ having a melting point ~~between 30-200 °C~~ from about 30 °C to about 200 °C and being included in an amount sufficient to further slow the release of the hydromorphone, said hydrophobic fusible carriers being fatty acids, fatty alcohols, or mixtures thereof;

heating the blend to a temperature sufficient to soften the mixture sufficiently to extrude the same; extruding the heated mixture as a strand having a diameter from ~~0.1-5~~ about 0.1 mm to about 5 mm;

cooling the strand; dividing the strand to form non-spheroidal multi-particulates of the extrudate having a length from ~~0.1-5~~ about 0.1 mm to about 5 mm; and

dividing the non-spheroidal multi-particulates into unit doses,

wherein the oral dosage form, when containing about 8 mg hydromorphone hydrochloride ~~or its pharmaceutically acceptable salt,~~ provides an in-vivo plasma concentration versus time curve (in the fed state) having an AUC from about 16.55 to about 21.47 ng·hour/ml, a C_{max} from about 0.65 to about 0.93 ng/ml, and a T_{max} from about 1.9 to about 4.1 hours.

89. (Previously Presented) The method of claim 87 or 88, further comprising extruding said heated mixture under vacuum conditions to provide a substantially non-porous extrudate.

90. (Previously Presented) The method of claim 87 or 88, wherein the hydrophobic fusible carrier has a melting point from about 45 °C to about 90 °C.

91. (Previously Presented) The method of claim 87 or 88, wherein a unit dose comprising an effective amount of the multi-particulates is compressed into a tablet.

92. (Previously Presented) The method of claim 87 or 88, wherein a unit dose comprising an effective amount of the multi-particulates is contained within a gelatin capsule.

93. (Currently Amended) The method of claim 87 or 88, further comprising blending a plasticizer with the hydromorphone hydrochloride ~~or its pharmaceutically acceptable salt~~, the one or more hydrophobic materials ~~material~~, and the one or more hydrophobic fusible carriers ~~carrier~~ prior to heating the blend.

94. (Previously Presented) The method of claim 93, wherein the plasticizer is selected from the group consisting of diethyl phthalate, tributyl citrate, triacetin, and mixtures thereof.

95. (Currently Amended) The method of claim 87 or 88, further comprising blending a lubricant with the hydromorphone hydrochloride ~~or its pharmaceutically acceptable salt~~, the one or more hydrophobic materials ~~material~~, and the one or more hydrophobic fusible carriers ~~carrier~~ prior to heating the blend.

96. (Previously Presented) The method of claim 95, wherein the lubricant is selected from the group consisting of magnesium stearate, stearic acid, talc, and mixtures thereof.

97. (Canceled)

98. (New) A method of treating a patient with a sustained-release dosage form comprising:

blending in an extruder hydromorphone hydrochloride together with: (1) one or more hydrophobic materials, said hydrophobic materials being acrylic and methacrylic acid polymers and copolymers; and (2) one or more hydrophobic fusible carriers having a melting point from about 30 °C to about 200 °C and being included in an amount sufficient to further slow the release of the hydromorphone, said hydrophobic fusible carriers being fatty acids, fatty alcohols, or mixtures thereof;

heating the blend to a temperature sufficient to soften the mixture sufficiently

to extrude the same;

extruding the heated mixture as a strand having a diameter from about 0.1 mm to about 5 mm;

cooling the strand; dividing the strand to form non-spheroidal multi-particulates of the extrudate having a length from about 0.1 mm to about 5 mm;

dividing the non-spheroidal multi-particulates into unit doses

administering on a daily basis said unit dose to the patient, wherein the oral dosage form, when containing about 8 mg hydromorphone hydrochloride, provides an in-vivo plasma concentration versus time curve (in the fasted state) having an AUC from about 15.83 to about 19.23 ng·hour/ml, a C_{max} from about 0.52 to about 0.76 ng/ml, and a T_{max} from about 3.9 to about 6.8 hours.

99. (New) A method of treating a patient with a sustained-release dosage form comprising:

blending in an extruder hydromorphone hydrochloride together with: (1) one or more hydrophobic materials, said hydrophobic materials being acrylic and methacrylic acid polymers and copolymers; and (2) one or more hydrophobic fusible carriers having a melting point from about 30 °C to about 200 °C and being included in an amount sufficient to further slow the release of the hydromorphone, said hydrophobic fusible carriers being fatty acids, fatty alcohols, or mixtures thereof;

heating the blend to a temperature sufficient to soften the mixture sufficiently to extrude the same;

extruding the heated mixture as a strand having a diameter from about 0.1 mm to about 5 mm;

cooling the strand; dividing the strand to form non-spheroidal multi-particulates of the extrudate having a length from about 0.1 mm to about 5 mm;

dividing the non-spheroidal multi-particulates into unit doses

administering on a daily basis said unit dose to the patient, wherein the oral dosage form, when containing about 8 mg hydromorphone hydrochloride, provides an in-vivo plasma concentration versus time curve (in the fed state) having an AUC from about 16.55 to about 21.47 ng·hour/ml, a C_{max} from about 0.65 to about 0.93 ng/ml, and a T_{max} from about 1.9 to about 4.1 hours.

100. (New) The dosage form of claim 70, wherein the AUC is about 15.83 ng·hour/ml, 19.0 ng·hour/ml or 19.23 ng·hour/ml, the C_{max} is about 0.52 ng/ml, 0.72 ng/ml or 0.76 ng/ml, and the T_{max} is about 3.9 hours, 5.6 hours or 6.8 hours.

101. (New) The dosage form of claim 71, wherein the AUC is about 16.55 ng·hour/ml, 20.1 ng·hour/ml or 20.47 ng·hour/ml, the C_{max} is about 0.65 ng/ml, 0.75 ng/ml or 0.93 ng/ml, and the T_{max} is about 1.9 hours, 2.4 hours or 4.1 hours.

102. (New) The method of claim 87, wherein the AUC is about 15.83 ng·hour/ml, 19.0 ng·hour/ml or 19.23 ng·hour/ml, the C_{max} is about 0.52 ng/ml, 0.72 ng/ml or 0.76 ng/ml, and the T_{max} is about 3.9 hours, 5.6 hours or 6.8 hours.

103. (New) The method of claim 88, wherein the AUC is about 16.55 ng·hour/ml, 20.1 ng·hour/ml or 20.47 ng·hour/ml, the C_{max} is about 0.65 ng/ml, 0.75 ng/ml or 0.93 ng/ml, and the T_{max} is about 1.9 hours, 2.4 hours or 4.1 hours.

104. (New) The method of claim 98, wherein the AUC is about 15.83 ng·hour/ml, 19.0 ng·hour/ml or 19.23 ng·hour/ml, the C_{max} is about 0.52 ng/ml, 0.72 ng/ml or 0.76 ng/ml, and the T_{max} is about 3.9 hours, 5.6 hours or 6.8 hours.

105. (New) The method of claim 99, wherein the AUC is about 16.55 ng·hour/ml, 20.1 ng·hour/ml or 20.47 ng·hour/ml, the C_{max} is about 0.65 ng/ml, 0.75 ng/ml or 0.93 ng/ml, and the T_{max} is about 1.9 hours, 2.4 hours or 4.1 hours.